DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 22, 2014

Shenzhen Mindray Bio-Medical Electronics Co., Ltd
c/o Ms. Yanhong Bai
Manager Regulatory Affairs, Technical Regulation Department
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen, 518057 P.R. China

Re: K143195
Trade/Device Name: Passport Series Patient Monitors (including Passport 17M, Passport 12M and T1)
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: Undated
Received: November 6, 2014

Dear Ms. Yanhong Bai,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): __K143195_____

Device Name: Passport Series Patient Monitors (including Passport 17M, Passport 12M and T1)

Passport 12M and 17M Patient Monitors:

The Passport 17M and Passport 12M patient monitors are intended for monitoring, displaying, reviewing, alarming, and transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), pulmonary artery wedge pressure (PAWP), cardiac output (C.O.), continuous cardiac output (CCO), mixed/central venous oxygen saturation (SvO_2/$ScvO_2$), carbon dioxide (CO_2), Oxygen (O_2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS), and respiration mechanics (RM). The equipment also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:

- The arrhythmia detection, ST Segment analysis of Mortara algorithm, BIS, RM, CCO, SvO_2/$ScvO_2$, and PAWP monitoring are intended for adult and pediatric patients only;
- ST Segment analysis of Mindray algorithm is intended for adult patients only;
- C.O. monitoring is restricted to adult patients only;
- ICG monitoring is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

T1 Patient Monitor:

The T1 Patient Monitor is intended for monitoring, displaying, reviewing, storing , alarming, and transferring of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable, arrhythmia detection, ST Segment analysis, and heart rate (HR)), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), pulmonary artery wedge pressure (PAWP), and carbon dioxide (CO_2). The equipment also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:

The arrhythmia detection, ST Segment analysis of Mortara algorithm, and PAWP monitoring are intended for adult and pediatric patients;

ST Segment analysis of Mindray ECG algorithm is intended for adult patients only;

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

1. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Passport Series Patient Monitors is provided below.

Device Common Name: Patient Monitor

Device Proprietary Name: Passport Series Patient Monitors (including Passport 17M, Passport 12M and T1)

Submitter:

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Date Prepared: November 4, 2014

Classification Regulation: 21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Panel: Cardiovascular

Classification Regulation, Classification Name and Product Codes:

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
Primary				

Product Code	**Regulation Number**	**Panel**	**Regulation Description**	**Device Common Name**
MHX	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, physiological, patient (with arrhythmia detection or alarms)
Secondary				
DSI	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	detector and alarm, arrhythmia
MLD	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, st segment with alarm
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	monitor, cardiac (incl. cardiotachometer & rate alarm)
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	system, measurement, blood-pressure, non-invasive
DSK	21 CFR 870.1110	Cardiovascular	Blood pressure computer	computer, blood-pressure
FLL	21 CFR 880.2910	Cardiovascular	Clinical electronic thermometer	thermometer, electronic, clinical
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	Oximeter
DPZ	21 CFR 870.2710	Cardiovascular	Ear oximeter	oximeter, ear
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer	analyzer, gas, carbon-dioxide, gaseous-phase
CBQ	21 CFR 868.1500	Anesthesiology	Enflurane gas analyzer	analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
CBS	21 CFR 868.1620	Anesthesiology	Halothane gas analyzer	analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBR	21 CFR 868.1700	Anesthesiology	Nitrous oxide gas analyzer	analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CCL	21 CFR 868.1720	Anesthesiology	Oxygen gas analyzer	analyzer, gas, oxygen, gaseous-phase
DSB	21 CFR 870.2770	Cardiovascular	Impedance plethysmograph	plethysmograph, impedance
DXG	21 CFR 870.1435	Cardiovascular	Single-function, preprogrammed diagnostic computer	computer, diagnostic, pre-programmed, single-function
OLW	21 CFR 882.1400	Neurology	Electroencephalograph	index-generating electroencephalograph software

Predicate Device: K132075 - PASSPORT M SERIES PATIENT MONITORING (INCLUDING MODELS PASSPORT 17M AND PASSPORT 12M), Mindray North America.

Indications for Use:

Passport 12M and 17M Patient Monitors:

The Passport 17M and Passport 12M patient monitors are intended for monitoring, displaying, reviewing, alarming, and transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), pulmonary artery wedge pressure (PAWP), cardiac output (C.O.), continuous cardiac output (CCO), mixed/central venous oxygen saturation (SvO_2/$ScvO_2$), carbon dioxide (CO_2), Oxygen (O_2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS), and respiration mechanics (RM). The equipment also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:

- The arrhythmia detection, ST Segment analysis of Mortara algorithm, BIS, RM, CCO, SvO_2/$ScvO_2$, and PAWP monitoring are intended for adult and pediatric patients only;
- ST Segment analysis of Mindray algorithm is intended for adult patients only;
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The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

T1 Patient Monitor:

The T1 Patient Monitor is intended for monitoring, displaying, reviewing, storing , alarming, and transferring of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable, arrhythmia detection, ST Segment analysis, and heart rate (HR)), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), pulmonary artery wedge pressure (PAWP), and carbon dioxide (CO_2). The equipment also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:

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ST Segment analysis of Mindray ECG algorithm is intended for adult patients only;

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

Device Description:

The subject Passport Series Patient Monitors includes three monitors:

- Passport 12M Patient Monitor
- Passport 17M Patient Monitor
- T1 Patient Monitor

All of the devices in the family are multiparameter monitors indicated for monitoring, displaying, reviewing, alarming, and transferring multiple physiological parameters. The Passport 12M and 17M Patient monitors provide patient monitoring capabilities based on the user selected modules that are plugged into the main monitor. The T1

patient monitor is one of the available modules that can be plugged into the Passport 17M or 12M monitor. The T1 can also be used as a standalone monitor and when used as a standalone monitor, it provides a subset of the functions that are provided by Passport 17M and 12M.

Each of the three monitors that are the subject of this 510(k) are modified versions of previously cleared Mindray devices. The Passport 17M and Passport 12M were previously cleared in K132075, on April 18, 2014 and the T1 was previously cleared in K123074 on July 3, 2013.

Performance Data:

- To establish the substantial equivalence of the Passport Series Patient Monitors (including Passport 12M, Passport 17M and T1), Mindray conducted functional and system level testing on the subject devices. The testing provided an evaluation of the performance of the device relevant to each of the modifications to the subject devices since their previous clearance. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.
- In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.
- Mindray has also followed the FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm issues on October 28, 2003.
- The T1 has been modified to provide wireless functionality. The existing wireless functionality of Passport 12M Monitor has been modified to include a new wireless module. The wireless capabilities of the Passport 17M remain unchanged. Mindray conducted Wireless functionality testing to ensure the performance of the new wireless modules meet specifications and are equivalent to the predicate device.

Substantial Equivalence:

Comparison of Indications - Both the predicate device and the subject family of devices are multiparameter patient monitors intended to be used in healthcare facilities under the direction of clinical professionals. The indications for use of the subject T1 device are a subset of those for the predicate device, as the T1 device includes a subset of the functionality. The indications for use of the Passport 12M, Passport 17M and T1 also include the new feature of 12-lead ECG interpretation. Although this feature is not present in the predicate device, it is present in the cleared Mindray V Series Monitoring System (K132026), and thus does not constitute a new intended use for a multi-parameter monitor.

Comparison of Technological Characteristics - The table below compares the key technological feature of the subject devices to the primary predicate device (the Mindray Passport Series M K132075). The features in grey are the features that have been modified since their previous clearances and that are the subject of this 510(k).

Device Comparison Table

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Integrated display and touchscreen	17" 1280*1024 pixels	12" 800*600 pixels	Same	Same	5", 480*272 pixels (same as K123074)
Secondary display	Independent control and display	Display is linked to integrated display	Same	Same	Independent display and control via a VGA port in the T1 docking station
Additional display features	The minitrends diagram, OxyCRG diagram, other monitor view, and calculation can be viewed when using an external LCD screen		Same	Same	Added
Wireless module (ASUS)	The ASUS module is used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).		Same	Added support for Silex wireless module	Added wireless function using the Cyberlink wireless module
Module rack	Independent of the patient monitor, provides 8 standard module slots to extend the measurement capabilities of the system		Same	Same	Not supported
Power supply	Two rechargeable Lithium-ion battery or AC power supply	One rechargeable Lithium-ion battery or AC power supply	Same	Same	One rechargeable Lithium-ion battery or DC power supply or AC power supply (same as K123074)

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh, 350 g		Same	Same	Chargeable Lithium-Ion, 7.4 VDC, 2500 mAh (same as K123074)
External memory card	Compact Flash		Same	Same	Secure Digital (same as K123074)
Data Recorder	The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.		Same	Same	Not supported
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation		Same	Same	Same
ECG	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, heart rate		Same	Same	Same
12-lead ECG interpretation	Not supported		Supported	Supported	Supported
ECG J-point auto detection	Supported		Same	Same	Added
Respiration rate (Resp)	Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm:±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified.		Same	Same	Same
Temperature (Temp)	Measurement range: 0 to 50°C (32 to 122°F) Accuracy: ±0.1°C or ±0.2°F (without probe)		Same	Same	Same

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Pulse oxygen saturation (SpO_2)	Mindray SpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode) 70 to 100%: ±3% (neonate mode) 0% to 69%: Not specified. Masimo SpO2 Module Measurement range: 1 to 100% Accuracy:70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified. Nellcor SpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.		Same	Same	Same

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Pulse rate (PR)	PR from Mindray SpO2 Module Measurement range: 20 to 254 bpm Accuracy:±3 bpm PR from Masimo SpO2 Module Measurement range: 25 to 240 bpm Accuracy:±3 bpm (measured without motion) ±5 bpm (measured with motion) PR from Nellcor SpO2 Module Measurement range: 20 to 300 bpm Accuracy:20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified PR from IBP Module Measurement range: 25 to 350 bpmbpm Accuracy:±1 bpm or ±1%, whichever is greater"		Same	Same	Same

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Non-invasive blood pressure (NIBP)	Measurement range: Adult Pediatric Neonate Systolic: 40 to 270 40 to 200 40 to 135 Diastolic: 10 to 210 10 to 150 10 to 100 Mean: 20 to 230 20 to 165 20 to 110 Accuracy: Max mean error: ±5 mmHg Max standard deviation: 8 mmHg		Same	Same	Same
Invasive blood pressure (IBP)	Measurement range: -50 to 300 mmHg Accuracy:±2% or ±1 mmHg, whichever is greater (without sensor)		Same	Same	Same
Pulse Pressure Variation (PPV)	Supported feature of IBP		Same	Same	Added
Cardiac output (C.O.)	The temperature change is displayed as a curve in the C.O. split screen, and the monitor calculates the C.O. value from this curve. The monitor is capable of storing 6 measurements.		Same	Same	Not supported
Continuous cardiac output (CCO)	CCO/SvO_2 interface module is used to interface with Edwards Vigilance II monitor / Vigileo Monitor which measures continuous cardiac output (CCO) and mixed venous oxygen saturation (SvO_2).		Same	Same	Not supported

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Mixed/central venous oxygen saturation (SvO_2/$ScvO_2$)	CCO/SvO_2 interface module is used to interface with Edwards Vigilance II monitor / Vigileo Monitor which measures mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$).		Same	Same	Not supported
Carbon dioxide (CO_2)	Sidestream CO2 Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 40 mmHg: ±2 mmHg 41 to 76 mmHg: ±5% of the reading 77 to 99 mmHg: ±10% of the reading Microstream CO2 Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 99 mmHg: ±5% of the reading ±5% of the reading+0.08% of (the reading-38) Mainstream CO2 Module: Measurement range: 0 to 150 mmHg Accuracy: 0 to 40 mmHg: ±2 mmHg 41 to 70 mmHg: ±5% of the reading 71 to 100 mmHg: ±8% of the reading 101 to 150 mmHg: ±10% of the reading"		Specifications unchanged Modules have been repackaged to occupy a single slot	Specifications unchanged Modules have been repackaged to occupy a single slot	Specifications unchanged Modules have been repackaged to occupy a single slot

	Predicate Device (K132075)		**Subject Devices**		
Feature	**17M**	**12M**	**17M**	**12M**	**T1**
Oxygen (O_2)	Oxygen values are calculated based on user input and not directly measured.		Same	Same	Not supported
Anesthetic gas (AG)	The AG module can identify two anesthetic gases in a mixture automatically and distinguish between them according to their contributions to the MAC value for display as the primary and secondary anesthetic agents.		Same	Same	Not supported
Impedance cardiograph (ICG)	Measurement range: SV: 5 to 250 ml HR: 44 to 2m C.O. 1.4 to 15 L/min Accuracy: SV: Not specified. HR: ±2 bpm C.O. Not specified."		Same	Same	Not supported
Bispectral index (BIS)	Measured parameters: EEG, BIS, BIS L, BIS R		Same	Same	Not supported
Respiration mechanics (RM)	Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm:±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified."		Same	Same	Not supported
3 Additional SpO_2 Sensors	None		The model names of the three SPO2 sensors are LNCS NeoPt, LNCS Neo, LNCS Inf. These three SPO2 sensors are cleared in K132037.		
4 New NIBP cuffs	None		The model names of the four NIBP cuffs are CM1306, CM1307, CM1506, CM1507. All this four NIBP cuffs are substantial equivalent to the NIBP cuffs which are cleared in K132075 and K092449.		
Supports T1 as a module	Not supported		Supported	Supported	N/A

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Passport M Series devices, the performance testing and conformance with applicable standards, the Passport Series Patient Monitors (including Passport 12M, Passport 17M and T1) can be found substantially equivalent to the predicate device.